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Paul A. Leipold
Patent Legal Staff
Eastman Kodak Company
343 State Street
Rochester, NY 14650-2201

EXAMINER	
DRODGE, JOSEPH W	

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/814,354
Filing Date: March 31, 2004
Appellant(s): MEHTA ET AL.

Andrew J. Anderson
<u>For Appellant</u>

EXAMINER'S ANSWER

This is in response to the appeal brief filed January 22, 2008 appealing from the Office action mailed July 19, 2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The claims have been rejected over Saim et al in view of Johnson et al and O'Connor et al (not O'Conner et al), a typographical error.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

PGPUBS US 2006/0124783 O'CONNOR ET AL 6-2006

PGPUBS US 2004/0091546	JOHNSON ET AL	5-2004
6,858,166	SAIM ET AL	2-2005

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saim et al patent 6,858,166 in view of Johnson et al PGPUBS Document US2004/0091546 and O'Connor et al PGPUBS Document US2006/0124783.

Saim et al disclose formation of micro or nano-particles by a process of admitting a supercritical fluid to a vessel, in which temperature and pressure are controlled (column 14, lines 21-45), agitating such vessel with a rotary agitator that may comprise an impeller of un-specified, given diameter relative to vessel diameter (column 14, line 63-column 15, line 6), introducing a 1st feed stream comprising a solvent and desired, active substance through a 1st introduction port and introducing a 2nd feed stream comprising the supercritical fluid through introduction ports both approximately within the highly agitated zone of the mixer that may be an impeller (see especially figures 1 and 2 and column 18, lines 30-63). ***The rotary impeller agitator inherently agitates material in the immediate vicinity therein at a more agitated, faster rate than material at progressive more distant locations from the impeller surfaces***. Both a first feed stream including particle-forming components and solvent and a second feed stream containing the supercritical fluid may be introduced proximate the agitated/highly agitated zone of the mixer (see column 12, lines 11-12 taken with lines 33-36 of column 12). Particles are then precipitated within such vessel over a carrier bed. A major use of the Saim process is to produce a wide variety of pharmaceutical particles (column 6, lines 42-53). ***Regarding inlet locations, a carrier bed may be formed by mixing carrier material with agitated, precipitated particles formed in the vessel (column 9, lines 43-49), and the zone of carrier material may cover any portion or the entirety of the vessel, with both the first stream of solvent and substance and second stream of supercritical fluid, or other gaseous or liquid solution, introduced anywhere***

within the carrier bed or above the carrier bed (figure 1, column 12, lines 8-36 and 54-61 and column 13, lines 14-33, also column 14, lines 5-14 and column 15, lines 15-22). Hence, the point of introduction of solvent stream and supercritical fluid stream may both be close to the agitating surfaces of the impeller agitator, or within a relatively highly agitated region of the mixing vessel.

The impeller or other agitator of the mixing vessel may be controlled to rotate at very high rotational speeds, so as to obtain high stirring intensity with vigorous stirring, hence induce turbulent mixing (column 12, lines 21-24, column 13, lines 50-51 and column 14, lines 30-32 and 62-65). ***Various forms of impeller and similar blades including pitched, curved, flat and helical designs may be employed in agitating. Column 15, lines 3-5 also states that plural "mixing devices may be employed".*** Temperatures, pressures and other parameters are controlled to obtain optimum performance (column 11, line 57-column 12, line 2). Precipitated particles are formed to be of nanoparticle size, hence inherently of a volume-average diameter in the range of 100 nanometers or less (column 17, lines 5-8 and 54-67). ***Also column 9, lines 43-49 states that particles having diameters as small as .001 micron (1 nanometer), or well within the claimed range of "smaller than 20 nanometers" may be formed. The vessel inherently facilitates more rapid and more turbulent mixing in the immediate vicinity of the impeller agitators grading to less rapid and less turbulent/ bulk mixing in zones further away from the impeller.***

The claims differ in requiring an explicit teaching of the particle formation and agitating vessel containing the impeller having two discrete mixing zones. However, O'Connor et al teaches to produce nanoparticles using solvents and supercritical fluids by use of conversion/mixing vessels that combine impeller mixers with other type stirrers, that have inlets for introducing solvents and other materials, and/or have a plurality of impeller mixers or impellers with differently functioning blades so as to create different mixing zones of different degrees of turbulence. See especially paragraph 33 and paragraphs 22-32 and 38-40 which are also pertinent. It would have been obvious to one of ordinary skill in the art to have adapted the more-complex configuration of mixing/agitating means of O'Connor in the process of Saim et al, or to have recognized the effect of having a plurality of mixing devices in creating different mixing zones, to effect greater, more complete mixing of components which are in slurry form, or mixing of materials of different phases (liquids, solids, semi-solids and gases).

The claims also differ in requiring the feed stream introduction ports to be located within one impeller diameter of the surface of the impeller agitator. However, Johnson et al teach production of nanoparticles using supercritical fluid processing in which the inlet tubes are within 15% of the agitator surface diameter (see especially paragraph 44, paragraphs 39-42,58 and 63 are also quite germane). ***In paragraph 17, Johnson states that solvent streams are advantageously located to introduce material "in a region near a mechanical agitator, where the mixing velocity is most easily controlled." Paragraph 58 of Johnson confirms that supercritical fluid may be introduced during the process of nanoparticle formation. Paragraph 66 additionally relates Johnson to Saim in stating that supplemental seed***

molecules may be used to facilitate the creation of nanoparticles upon micromixing and that such seed material may comprise pharmaceutically acceptable carrier material.

It would have been further obvious to one of ordinary skill in the art to have located the end of the inlet tubes of Saim et al very close to the impeller agitators as suggested by Johnson et al, to facilitate rapid incorporation of the incoming fluid into the swept region of the agitator and rapid mixing, and to have more readily controlled mixing velocity so as to achieve result of better control of size range of formed nanoparticles.

Regarding dependent claims, Saim also discloses the following: for claims 3, 6 and 7, flow of particles exhausted to an expansion or collection chamber that may constitute a distributor (column 21, lines 10-17), use of capillaries for claim 5 (column 13, line 15), for claim 8 forming of a dispersion (column 6, line 34), for claims 9-14 forming of nanosize particles of relatively uniform particle size (column 17, lines 5-8 and column 7, lines 6-8), and for claims 15-18 forming of a wide range of pharmaceutical and industrial particles including the instantly claimed species (column 16, lines 33-45); paragraph 42 of O'Connor is also quite pertinent to claims 15-18.

Regarding claims 2 and 4, Saim discloses a steady-state operation of processing and agitation in the mixing/processing vessel (paragraph 14, lines 46-50) and illustrates a back-pressure regulator in the outlet from the processing vessel at the Mode 2 illustration of Figure 1.

Also paragraph 42 of Johnson describes a steady-state operation with a maintained flow balance between incoming streams and collected streams.

(10) Response to Argument, reference to "O'Conner" in the Argument heading, is considered a reference to "O'Connor" (see Grounds of Rejection)

Arguments directed against primary reference Saim:

It is argued that in Saim, mixing or agitation is not required, and that the disclosed process of Saim is directed towards coating of precipitated particles, rather than the precipitation of particles. It is submitted that Saim extensively discloses advantages and desirable effects of agitating regarding blend uniformity and employment to maintain the carrier bed in a mixed state (see for instance column 7, lines 63-67 and column 9, lines 43-56). Further, Saim is firstly concerned with the precipitation steps of producing small particles, as in the other teaching references and instant Specification; coating of the particles is optional and one of several possible embodiments of Saim (see the Abstract of Saim).

Appellant asserts that Saim does not produce particles with size of less than 20 nm. However, Saim (column 9, lines 39-41) discloses produced particles of size as small as 1 nm.

It is argued that Saim simply does not teach entry of separate streams of solution and pressurized gaseous fluid into a highly agitated zone of an impeller agitator and primarily disclose introduction of only a single pressurized stream rather than separate first and second streams. It is submitted that in Mode 2 of the Saim disclosure, separate pressurized streams of gaseous fluid (supercritical fluid) and organic solution are utilized and that either or both of these streams may be configured for entry of fluid/material into the mixed carrier powder bed and thus close to the impeller agitator(s), (see figure 1, column 12, lines 26-36 and 54-61 and column 13, lines 30-33 and column 14, lines 5-14). Appellant asserts that there is simply no suggestion in Saim to introduce both feed streams into a created highly agitated zone close to the impeller agitator surface. However, introduction of the feed streams into the carrier material would necessarily bring their points of introduction relatively close to the surfaces of the one or more impeller agitators employed.

Argument directed against combining teachings of Saim, O'Connor and Johnson. It is argued at top of page 7 of the Brief that the references are directed towards obtaining different specific results. However, all three applied references are similarly directed towards precipitation and other processing of microparticles and nanoparticles utilized in the production of pharmaceutical products, and similarly employ organic solutions and supercritical fluids.

Argument directed against O'Connor:

It is argued that O'Connor is directed towards size reduction of pre-made macro particles rather that direct precipitation of small sized particles as in Saim. O'Connor is directly germane to the process of Saim; Saim likewise concerns particle size reduction as column 4, lines 4-40 deals with deagglomeration associated with the precipitation to reduce produced particle sizes as well as direct precipitation of microparticles and nanoparticles.

Argument directed against Johnson:

It is acknowledged that the teaching in Johnson of employing inlet tubes which are within 15% of an agitator surface were well known prior art mixing technology; however it was not known to employ such type mixing technology in an "SAS type particle formation process and instead utilized conventional liquid solvents and amphiphilic co-polymers. Appellant states that Johnson employs liquefied gas instead of supercritical fluid in the processing.

It is submitted that Johnson is silent as to the terminology "SAS-type particle formation" , while Saim utilizes any of a wide range of precipitation mechanisms including "SAS" and other mechanisms (Saim at column 12, lines 36-38). Both Johnson and Saim employ organic solvents (paragraph 37 of Johnson) and both employ supercritical fluids (paragraph 63 of Johnson referring to use of supercritical fluid both during and after the nanoparticle formation process).

It is argued that Johnson actually teaches that an agitator is not even required in the disclosed process if the fluids are added together at a high enough mixing velocity. Paragraphs 13-16 of the Johnson Summary of the Invention extensively concern types of mixers that may be employed and describe advantages of utilizing rapid mixing to control produced particle sizes and enhance blend uniformity which are in common with goals of Saim (column 7, lines 15-20), especially in continuous flash mixing processes

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Joseph W. Drodge/

Primary Examiner, Art Unit 1797

Conferees:

/David R. Sample/
David R. Sample
Supervisory Patent Examiner, Art unit 1797

/Duane S. Smith/
Duane Smith
Supervisory Patent Examiner, Art unit 1797